



1637

#10 1208
11/19/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rakesh Anand et al. Art Unit : 1637
Serial No. : 09/857,129 Examiner : Shar S. Hashemi
Filed : August 24, 2001
Title : USE OF FACTOR X POLYMORPHISM IN THE DIAGNOSIS AND
TREATMENT OF FACTOR X AND/OR FACTOR XA MEDIATED DISEASES

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the action mailed October 3, 2002, Applicants elect the invention of Group 1 (claims 1-3) drawn to a method of diagnosis of a single nucleotide polymorphism in a Factor X gene in a human. This election, however, is made with traverse.

Applicants respectfully disagree with the restriction of Group 1, Group 2 (claims 4-5) and Group 3 (claims 10-11) based on the Unity of Invention Rules. Examiner states, "According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity" (page 3 of the Office Action). Applicants believe that Examiner has misapplied this section to the present case, as the restriction was not in fact made among members of an actual Markush group. Section (f) of Annex B of the PCT Administrative Instructions defines "the so-called "Markush practice" wherein a single claim defines alternatives..." (emphasis added). Groupings of claims are not "Markush Groups."

Furthermore, Applicants note the Examiner's recognition of one common property of Groups 1 to 3 of being "drawn to methods involving active steps" (page 3, paragraph 2 of the Office Action). Thus, by Examiner's own admission, the methods of Groups 1, 2 and 3 do share a common property.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit

Signature

Typed or Printed Name of Person Signing Certificate

RECEIVED

NOV 15 2002

TECH CENTER 1600/2900

November 4, 2002

Joanne D Boyle

Joanne D. Boyle

In addition, Examiner distinguishes Group 1, “drawn to a method of diagnosis or screening,” from Group 2, “drawn to method of predictive response to therapeutics,” and also from Group 3, “drawn to a method of treatment using antagonistic drug” (page 3, paragraph 3 of the Office Action). Applicants submit that the claims of Group 2 depend from Group 1 and therefore Groups 1 and 2 should be rejoined. Applicants also submit that the methods of treatment of claims 10 and 11 (Group 3) include a diagnosis step based upon the method as claimed in claim 1 (and, in fact, at least claim 10 could have been written as dependent on claim 1 with no change in scope). It appears that the search carried out with respect to claim 1 will reveal prior art relevant to claims 10 and 11 as well. Applicants submit that there would be no burden whatsoever on the Examiner if one were to include claims 10 and 11 in the same group as claims 1-5. Applicants strongly protest the restriction and request that at least Groups 1, 2 and 3 be combined for further examination.

Applicants also wish to address Examiner's comments regarding prior art. The Examiner states:

The “special technical feature” of Groups 1-6 is a core common structure that is derived from the sequence of the parent Factor X gene which is shown by Cargill et al. (Nature Genetics, 22, 231-239, 1999) to lack novelty or inventive step of detecting single nucleotide polymorphism in human Factor X at exon 5 position 41 and exon 7 position 57 and does not make a contribution over the prior art (pages 2-3 of the Office Action).

Applicants point out that the instant application is a PCT/USA National Phase Application based on International Application Number PCT/GB99/03973. The earliest claimed priority date for this application is December 5, 1998, and therefore Cargill et al. is not prior art to this application.

Applicant : Rakesh Anand
Serial No. : 09/857,129
Filed : August 24, 2001
Page : 3

Attorney's Docket No.:
06275-294001 /LDG/Z70433-1P US

No fees are believed to be due. Please apply any charges or credits to Deposit Account
No. 06-1050.

Respectfully submitted,

Date:

Nov. 4, 2002

Janis K. Fraser

Janis K. Fraser, Ph.D., J.D.
Reg. No. 34,819

7037

Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906